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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,178	10/28/2003	J. Daniel Raulerson	MED0065	4287
33941	7590	04/27/2011		
Fox Rothschild LLP Blue Bell 997 Lenox Drive Building 3 Lawrenceville, NJ 08648-2311			EXAMINER VU, QUYNH-NHU HOANG	
			ART UNIT 3763	PAPER NUMBER
			NOTIFICATION DATE 04/27/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary

Application No.

10/695,178

Applicant(s)

RAULERSON ET AL.

Examiner

QUYNH-NHU H. VU

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-912)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The amendment filed on 03/29/11 has been entered in the case. Claims 34-38 are pending for examination and claims 1-33 have been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Consalvo (US 4,098,275) in view of either Cianci (US 4,149,539) or Raulerson (US 4,037,599).

Regarding claim 34, Consalvo discloses a multiple catheter assembly shown in Fig. 7 comprising:

a first catheter 1 having a first distal end region 1 and a first proximal end region (at portion of element 16, see Fig. markup below) joined by a first intermediate section 11;

a second catheter 7 having a second distal end region 9 and a second proximal end region (at portion of element 15, see Fig. markup below) joined by a second intermediate section 5;

first and second extension tube assemblies 17 and 18 having first and second distal end portions respectively associated with the first and second proximal end regions of the first and second catheters;

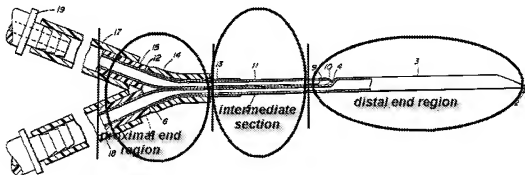
a hub member 14 located around the first and second proximal end regions of the first and second catheters distally of the proximal ends thereof.

As to the limitation "after catheter implantation and subcutaneous tunneling and at a site selected by the practitioner along coextending lengths of the first end second proximal end regions spaced from the proximal ends thereof" this is a functional limitation which only requires the ability to so perform. In this case, Consalvo discloses a device and method for supporting the flow of blood such as introduction or removal of blood, as in a hemodialysis. As seen in Fig. 7, Consalvo clearly shows that subcutaneous

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tunneling of a catheter at a site selected by the practitioner along coextending length of the first and second proximal end regions spaced from the proximal ends thereof. The step of implantation catheter is very well-known in the hemodialysis art so that the user can perform dialysis frequently. The device of Consalvo is capable of implantation as for intended use purpose (i.e., performing hemo-dialysis).

Consalvo further discloses that portions of the proximal end regions (at portions of element 15, 16) of the first and second catheters 1 and 7 extend through a hub member 14 and proximally beyond the proximal end of the hub member through respective exits and spaced apart from each other, to be connected to respective ones of the first 17 and second 18 extension tube assemblies, with other portions of the proximal end regions of the first and second catheters extend distally from the hub member separately from but adjacent to each other, see Fig. 1.



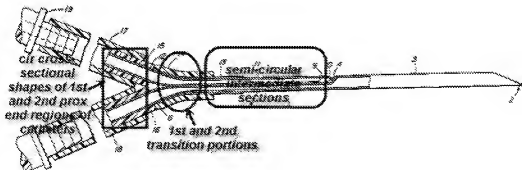
It has been held that the recitation "adapted to/capable of to be releasably attachable by a practitioner..." performing a function is not a positive limitation but only requires the ability to so perform. In re Hutchison, 69 USPQ 138. In this case, as seen in Fig. 1 or 7 of Consalvo, the hub member 14 of Consalvo is attachable but is not releasable. However, claim 34 only requires that the hub member is adapted to be releasably attachable by a practitioner. Therefore, the hub member of Consalvo can be used or modified with another releasably attachable hub member of either Cianci or Raulerson.

Cianci discloses a catheter assembly comprising: a catheter 20; a hub member 18; wherein the catheter 20 is removably and attachable to the hub member 18 by a practitioner directly to and around the proximal regions of the catheter 20.

Raulerson discloses a catheter assembly comprising: a catheter 14, an initially separate hub member 12; wherein the hub member 12 comprises a hinge line folding of one hub portion relative to the hinge line into mating engagement with other hub portion will serve to open or close, see col. 3, lines 40-45, and Fig. 3. In other words, the hub member of Raulerson is adapted to be releasably attachable by a practitioner. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Consalvo with a hub assembly, as taught by either Cianci or Raulerson, for the benefit of easy attachability or detachability between the catheter device and the hub member.

Regarding claim 35, Consalvo discloses that the rear portion or coupling end 6 of the venous tube (or first catheter) 1 has a circular cross-sectional area, col. 4, lines 9-10 and see Fig. 2. As seen in Fig. 1, the rear portion 12 of arterial tube (or second catheter) 7 has identical cross-sectional area as that of the rear portion 6 of the first catheter 1, the cross-sectional shapes of the first 6 and second 13 proximal end regions are circular, and the cross-sectional shapes of the first and second distal end portions of the first 17 and second 18 extension tube are circular, see Figs. 1 and 2.

Regarding claim 36, Consalvo discloses that the cross-sectional shapes of the first and second intermediate sections 5 and 11 of the first and second catheters 1 and 7 are semicircular (see Fig. 5 or col. 4, lines 2-5 and lines 31-33). According to Fig. 1, Consalvo shows that the transition sections are located in between the first and second proximal end regions of the catheters and the first and second intermediate sections 5 and 11, as shown in the marked up figure below.



Regarding claims 37-38, Consalvo discloses that the first and second intermediate sections 1 and 5 of the first and second catheters 1 and 7 are splittably joined to each other; wherein the first and second intermediate sections 11 and 5 of the first and second catheters 1 and 7 are splittably joined to each other by adhesive, col. 6, lines 54-56 and see Fig. 5.

Response to Arguments

Applicant's arguments filed 03/29/11 have been fully considered but they are not persuasive.

1) Applicant argues that the reference does not disclose an implantable catheter nor subcutaneous tunneling, nor a releasable hub, and the reference fails to disclose that the practitioner selects the site for a hub or secures the hub to the needle device.

In response, the device of Consalvo is used in hemodialysis, therefore, the device of Consalvo is capable of implanting. Consalvo clearly discloses in Fig. 7 that the catheter device is inserting or subcutaneous tunneling under skin. Consalvo discloses the catheter device comprising a hub member 14 is attached to the catheter device but not releasable. However, either Ciani or Raulerson clearly discloses a hub member is releasable and attachable to a catheter device. The references are analogous in the art and with the instant invention; therefore, a combination of Consalvo as modified either Ciani or Raulerson is proper. As further to the limitation "the practitioner selects the site for a hub or secures the hub to the needle device" is considered as a functional limitation which only requires the ability to so perform. Examiner clearly point out that the device of Consalvo is ability to perform this limitation, see above for more detail.

2) Applicant further argues that Ciani fails to disclose two lengths of catheter tubing extending from distal end portion through the hub to proximal end portions proximally beyond the hub, only one tubing length extends distally from the hub, although two proximal tubing portions extend proximally therefrom.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800

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F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the limitation as mentioned above is disclosed in the primary reference Consalvo. Consalvo discloses that the hub member attachable but not detachable to the catheter device. Meanwhile, the Cianci clearly discloses the hub member is attachable and detachable to the catheter device. Since the references are analogous in the art and with the instant invention, therefore, a combination is proper. Therefore, one skill in the art would recognize that the device of Consalvo as modified by Cianci for the benefit of easy attachability or detachability between the catheter device and the hub member.

3) Applicant further argues that Raulerson fails to disclose a releasably coupleable hub securable to two catheter lengths by the practitioner.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the limitation as mentioned above is disclosed in the primary reference Consalvo. Meanwhile, the Raulerson clearly discloses the hub member is attachable and detachable to the catheter device. Since the references are analogous in the art and with the instant invention, therefore, a combination is proper. Therefore, one skill in the art would recognize that the device of Consalvo as modified by Raulerson for the benefit of easy attachability or detachability between the catheter device and the hub member.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

/Quynh-Nhu H. Vu/
Examiner of Art Unit 3763